

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Photoactivatable liposomal nanoparticle for the delivery of an immunotherapeutic or immunotherapeutic-enabling agent.

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Nano Red LLC ("Nano Red") located in Milwaukee, Wisconsin.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Jasmine Yang, Sr. Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: jasmine.yang@nih.gov.

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SUPPLEMENTARY INFORMATION:

Intellectual Property

- 1. U.S. Provisional Patent Application (Application No. 61/845,861) filed July 12, 2013, HHS Reference No.: E-482-2013/0-US-01
- 2. PCT Application (Application No. PCT/US2014/045922) filed July 09, 2014, HHS Reference No.: E-482-2013/0-PCT-02
- 3. Canada Patent Application (Application No. 2917545) filed 09 July 2014, HHS Reference No.: E-482-2013/0-CA-03
- 4. European Patent Application (Application No. 14745037.3) filed 09 July 2014, HHS Reference No.: E-482-2013/0-EP-04
- 5. U.S. Patent Application (Allowed Application No. 14/904,385) filed January 11, 2016, HHS Reference No.: E-482-2013/0-US-05

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be where patent applications are filed and the field of use may be limited to "Photoactivatable liposomal nanoparticle for the delivery of an immunotherapeutic or immunotherapeutic-enabling agent". Additional licensable fields of use are available (e.g. encapsulating imaging agent).

This technology discloses a photoactivatable, lipid-based nanoparticles containing at least one hydrophilic agent, wherein the agent could be an anti-cancer agent, an imaging agent, or an anti-inflammatory agent and the lipid bilayer wall of the nanoparticle is comprised of (i) a lipid bilayer comprising (a) 1,2-bis(tricosa-10,12-diynoyl)-sn-glycero-3-phosphocholine (DC8,9PC), (b) 1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-methoxy(polyethylene glycol) (DSPE-PEG) and (c) dipalmitoylphosphatidylcholine (DPPC), and (ii) a tetrapyrollic photosensitizer, 2-[1-

hexyloxyethyl]-2-devinyl pyropheophorbide-a (HPPH), and wherein the encapsulated

agent is released by exposure to near-infrared light.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The

prospective exclusive license will be royalty bearing, and the prospective exclusive

license may be granted unless within fifteen (15) days from the date of this published

notice, the National Cancer Institute receives written evidence and argument that

establishes that the grant of the license would not be consistent with the requirements of

35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments

and objections, other than those in the form of a license application, will not be treated

confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to

contain business confidential information and any release of information in these license

applications will be made only as required and upon a request under the Freedom of

Information Act, 5 USC 552.

Dated: August 31, 2018.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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